



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1459
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,425	09/27/2001	Rui Saito	214375US0	8762
22850	7590	12/19/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			REDDICK, MARIE L	
			ART UNIT	PAPER NUMBER
			1713	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,425

Applicant(s)

SAITO ET AL.

Examiner

Judy M. Reddick

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-28 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/03 has been entered.

Election/Restrictions

2. Claims 3-7 & 9-23 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8.

Specification

3. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper (page 7, lines 7-9). Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The recited "the radiation-resistant medical adhesive product" per claim 8 constitutes indefinite subject matter as per the non-express establishment of proper antecedent basis. It is suggested that applicants use the indefinite article "a" in lieu of the definite article "the".

B) The recited "the amount solid content" per claim 26 constitutes indefinite subject matter as per said phrase engendering awkwardly expressed claim language. It is suggested that applicants delete "amount".

C) The recited "the adhesion" per claim 27 @ line 1 constitutes indefinite subject matter as per the non-express establishment of proper antecedent basis. It is suggested that applicants delete the indefinite article "the".

D) The recited "80 to 100% of that before irradiation" per claim 27 constitutes indefinite subject matter as per the metes and bounds of "that" engender indeterminacy in scope. It is not clear as to what "that" is referring to. Moreover, does the "80 to 100%" imply that the adhesion is better than the adhesion before irradiation?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 8 & 25-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bernard et al(U.S. 5,130,375).

As to claims 8 and 25-28, Bernard et al teach(8) a method for sterilizing a radiation-resistant medical adhesive product comprising an acrylic polymer(the Abstract, col. 1, line 68, col. 6, lines 24-68 and Runs 5 and 6) and a radiation-resistant agent selected from the group consisting of rosin, a hydrogenated rosin, a disproportionated rosin, a polymerized rosin, a modified rosin ester, terpene resin, terpene phenol resin, aromatic modified terpene resin, hydrogenated terpene resin, aliphatic petroleum resin, aromatic petroleum resin, copolymerized petroleum resin, alicyclic petroleum resin, hydrogenated petroleum resin and alkyl phenol resin(the Abstract, col. 2, lines 7-35, col. 3, lines 7-68, col. 4, lines 1-68, col. 5, lines 1-68, col. 6, lines 1-23, Runs 5 & 6), wherein said method comprises sterilizing said radiation-resistant medical adhesive product with radiation wherein said radiation is with either gamma-rays or electron rays(the Abstract, col. 2, lines 1-3 & 66-68 and Runs 5 and 6); (25) the method wherein said radiation is with electron rays(the Abstract, col. 2, lines 3 & 66, col. 7, line 19 and Runs 5 and 6); (26) the method wherein the solid content of the radiation-resistant agent is 5 to 100 parts by weight relative to 100 parts by weight solid content of the acrylic polymer(col. 2, lines 36-42, col. 7, lines 9-21 and Runs 5 & 6); (27) the method wherein the adhesion of the adhesive product after irradiation with 60 kGy dose of electron rays is 80 to 100% of the adhesion before irradiation(col. 2, lines 66-68 and line 7, line 21-24); and (28) the method wherein the adhesive product is selected from the group consisting of adhesive tapes, adhesive plasters, adhesive sheets, adhesive labels, adhesive packaging bags, first-aid adhesive tapes, first-aid adhesive plasters and surgical drapes(col. 3, lines 1-5). Bernard et al therefore anticipate the instantly claimed invention. As to the adhesive property per claim 27, it would be expected that this property would be met by Bernard et al who

teach that doses of electron beam radiation of 50 kGy and higher are operable within the scope of patentees invention, with the understanding that "higher" is relative and not absolute and includes doses of irradiation of 60 kGy. As to any remaining properties, it would be expected that the sterilized adhesive of Bernard et al would possess the claimed properties since the sterilized adhesive product of Bernard et al is essentially the same as and made in essentially the same manner as applicants' adhesive product. The onus to show that this, in fact, is not the case is shifted to applicants under the guise of *In re Fitzgerald*(619 F.2d 67, 205 USPQ 594 (CCPA 1980)). Moreover, the discovery of a new property"(radiation resistant") or use for a previously known compound/composition cannot impart patentability to the claims, even if the property or use is unobvious from the prior art as provided for under the guise of *In re Schoenwald*(22 USPQ 1671). Even if it turns out that the claimed invention is not anticipated, it would have been obvious to the skilled artisan to extrapolate, from the disclosure of Bernard et al, the precisely defined method of sterilizing an adhesive product, as claimed, as per such having been within the general purview of the disclosure of Bernard et al and with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernard et al(U.S. 5,130,375) in combination with Saito et al(U.S. 5,429,590).

The disclosure of Bernard et al for what it teaches and applied to claims 8 & 25-28 as stated in the Grounds of Rejection supra. Further, the disclosure of Bernard et al differs

basically from the claimed invention as per the non-express teaching of an embodiment directed to the use of radiation with γ -rays. However, Saito et al teach the use of radiations such as electron rays and γ -rays for sterilizing medical adhesives derived from a tackified-acrylic-based adhesive(col. 7, lines 54-63, col. 11, lines 61-68, col. 12, lines 1-2, col. 13, lines 14-32 & col. 16, lines 11-39). Therefore, it would have been obvious to the skilled artisan to use the γ -rays taught as an equivalent to electron rays per the disclosure of Saito et al in lieu of or in addition to the electron rays taught by Bernard et al, based on their equivalently disclosed scope, for the sterilization of the acrylic-based adhesive compositions of Bernard et al and with a reasonable expectation of success. Criticality for such, commensurate in scope with the claims, not having been demonstrated on this record.

Response to Arguments

11. Applicant's arguments, filed 11/20/03, with respect to the rejection(s) of claim(s) 8 under 35 USC 102(b)/103(a) over Traynor et al(U.S. 4,726,982) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bernard et al under 35 USC 102(b)/103(a) and Bernard et al in combination with Saito et al under 35 USC 103(a).

Conclusion

12. Applicants are herein apprised that it has come to the Examiner's attention that information such as Date, Name and Classification qualifying the U. S. Patent Documents listed on pages 2 and 3 of FORM PTO-892 of September 05, 2002 was inadvertently omitted. Attached to the current Office Action is a corrected copy of the FORM PTO-892 listing the information as relates to each Document. Documents US-5,199,979 and 5,695,837 were listed in duplicate and/or cited in an earlier FORM PTO-892. Copies of all prior art Documents were previously furnished along with a previous Office Action(09/05/02). An apology is extended to applicants for any inconvenience that this may have caused. The additional prior art to HITACHI CHEM CO(JP 59-018774) listed on the attached FORM PTO-892 is cited as of interest in teaching radiation-

Application/Control Number: 09/963,425

Page 7

Art Unit: 1713

curable pressure sensitive adhesive compositions and is considered cumulative to the prior art *supra*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (703)308-4346. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703)308-2450. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-8183.

Judy M. Reddick
Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR JMR
12/11/03